Drug Policy:

Darzalex™ and Darzalex Faspro™ (daratumumab IV/SC)

POLICY NUMBER UM ONC_1280	**SUBJECT** Darzalex™ and Darzalex Faspro™ (daratumumab IV/SC)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 03/23/16, 01/05/17, 01/10/18, 01/09/19, 12/11/19, 01/08/20, 05/13/20, 06/10/20, 08/12/20	**APPROVAL DATE** August 12, 2020	**EFFECTIVE DATE** August 28, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 03/23/16, 01/05/17, 01/10/18, 01/09/19, 12/11/19, 01/08/20, 05/13/20, 06/10/20, 08/12/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Darzalex and Darzalex Faspro (daratumumab IV/SC) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

B. Multiple Myeloma

1. NOTE #1: The preferred anti-CD38 agent for Multiple Myeloma, per NCH policy and NCH pathway, is Darzalex and Darzalex Faspro (daratumumab IV/SC) over Isatuximab.
2. NOTE #2: Subcutaneous daratumumab, Darzalex Faspro, may be substituted for IV daratumumab, for all the indications listed in this policy.
3. Daratumumab use is supported for multiple myeloma as follows:
   a. First line therapy for members with newly diagnosed, non-transplant eligible myeloma:
      i. In combination with Lenalidomide + Dexamethasone.
   b. In members with relapsed/refractory myeloma, Daratumumab use is supported in any one of the following :
      i. Initial therapy for relapsed/refractory myeloma:
         - Daratumumab + Lenalidomide + Steroid (DRd) OR
         - Daratumumab + Bortezomib + Steroid (DVd)

C. Both the above regimens are the preferred regimens per NCH Pathway & NCH Policy

1. Subsequent therapy for relapsed/refractory myeloma:
   a. Single agent Daratumumab therapy in members who have experienced disease progression on both a proteasome inhibitor and an immunomodulatory agent OR have experienced disease progression on 3 prior treatment regimens.

III. EXCLUSION CRITERIA

A. Disease progression while on a Darzalex and Darzalex Faspro (daratumumab IV/SC) containing regimen.

B. Dosing exceeds single dose limit of Darzalex IV 16 mg/kg or Darzalex SC 1800 mg.

C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Darzalex PI prescribing information. Janssen Biotech, Inc. Horsham, PA 2020.

B. Darzalex Faspro PI prescribing information. Janssen Biotech, Inc. Horsham, PA 2020.

C. Clinical Pharmacology Elsevier Gold Standard 2020.

D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2020.

F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2020.